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Lori Artim
Regulatory Affairs – NAFTA

September 24, 2002

Mr. Leonard Cole
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
Document Processing Desk (EUP)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

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**Re: Application for Experimental Use Permit for Field Testing of the Plant-Incorporated
Protectant *Bacillus thuringiensis* VIP3A Insect Control Protein as Expressed in Event COT102
Cotton Plants**

Dear Mr. Cole:

Syngenta has developed a new cotton line that expresses an insect control protein designated VIP3A. VIP3A is one of a novel class of recently discovered insecticidal proteins that occur naturally in *Bacillus thuringiensis* (Bt). The VIPs (vegetative insecticidal proteins) are produced during vegetative bacterial growth and are secreted as soluble proteins into the extracellular environment.

Other than its demonstrated insecticidal activity, VIP3A is not known to have any other biological or catalytic function. Although VIP3A protein shares no homology with known Cry proteins, extensive testing has established that VIP3A is similarly very specific in its activity, and has demonstrated toxicity only to the larvae of certain lepidopteran species, including key pests of cotton. Further, because VIP3A appears to target a different receptor than Cry proteins in sensitive species, it represents a potentially useful tool in the prevention or management of pest resistance to Cry proteins.

Upon commercial introduction, the use of transgenic VIP3A cotton plants is expected to offer an important new option in lepidopteran pest control and integrated pest management programs. Moreover, VIP3A cotton will be an attractive, biologically based alternative to the use of foliar insecticides. The use of VIP3A cotton plants is expected to offer substantial environmental and worker safety benefits associated with the reduced need for broad-spectrum insecticides. Additionally, benefits to cotton growers will likely include greater profitability, convenience and predictability in producing a high-yielding cotton crop.

VIP3A-expressing cotton plants derived from transformation event COT102 have been field tested under USDA Notifications and in compliance with the guidelines for USDA-regulated plantings in 2000, 2001, and 2002. The overall results of those trials have indicated that cotton plants derived from event COT102 have significant and specific insecticidal activity against several lepidopteran pests including, but not limited to, *Helicoverpa zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm), *Spodoptera frugiperda* (fall armyworm), *Spodoptera exigua* (beet armyworm), and *Trichoplusia ni* (cabbage looper).

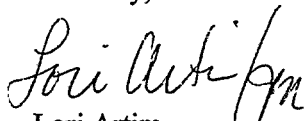
As results to date have been most promising, Syngenta believes large-scale field-testing is now required in order to continue our evaluations of event COT102-derived VIP3A cotton. Accordingly, Syngenta is requesting an Experimental Use Permit valid for February 14, 2003 through February 14, 2004. Depending on local weather conditions, planting often begins in the southern regions of the US cotton belt in mid March. Taking into consideration the time that will be required to obtain State approvals upon issuance of the EUP, we kindly ask that this EUP be approved no later than February 14, 2003. No food or feed tolerances or tolerance exemptions are being requested at this time.

The proposed plantings will take place in twelve states and will consist of a maximum of 904.5 acres. A description of the proposed activities and associated acreage by state and county is provided in Section G of the enclosed EUP application. Also accompanying this application are several data volumes and summary volumes that provide data and information relevant to the characterization of the VIP3A protein, the selectable marker protein, and event COT102 cotton plants; the mammalian safety of the introduced proteins; and the environmental safety and fate of the introduced proteins. Additional data will be submitted concurrently with a future application for Section 3 registration.

At this time, we are requesting that the EUP be granted with the allowance for retaining all seed produced for future experimental work and for future seed production activities under an approved Section 3 registration. The residual cotton plant ginning wastes (cotton gin by-products) will be managed under crop-destruct practices. Finally, the cleaned cotton lint (fiber that has been mechanically cleaned to remove non-fiber plant material) will be sold commercially, as this commodity is not used as a food or feed item. Additionally, our data demonstrate that the VIP3A protein is not expressed in the cotton fiber and, therefore, will not present any exposure potential.

Syngenta Seeds makes no claims of Confidential Business Information (CBI) for the contents of this letter. Additionally, no specific CBI claims have been made for the accompanying data on the basis of its falling within the scope of FIFRA Section 10(d)(1)(A), (B), or (C). If you have any questions regarding this application, please do not hesitate to contact me.

Sincerely,



Lori Artim
Regulatory Affairs Manager
Syngenta Seeds, Inc.

Enclosures

cc: Janet Andersen, BPPD/OPP/EPA
Phil Hutton, BPPD/OPP/EPA
Jeffrey Stein, Syngenta Seeds
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